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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,747	12/15/1998	ROBERT E BRIGGS	0029577957	4952

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/210,747	Briggs et al
Examiner	**Group Art Unit**
Portner	1645

☒ Responsive to communication(s) filed on *Feb 13, 2001* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *40-44, 46-49, and 51-62* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *40-44* is/are allowed.

☒ Claim(s) *46-49 and 51-62* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 34-35,38-39, 45 and 50 have been canceled.

Claims 40-44,46-49, 51-62 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2. The terminal disclaimer submitted April 7, 2000 has been processed and found proper, the rejection of claims 40-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,849,305 for reasons of record, as well as claim 5 of US Pat. 5,824,525 and claims 13-16 of US Pat. 5,587,305 is herein withdrawn.

3. Claims 43-44 rejected under 35 U.S.C. 112, second paragraph, for reciting modes of administration of the composition but these limitations are not further limiting of the claim from which they depend because a mode of administration does not further define the components present in the composition being claimed and the recitation of an intended use does not define a vaccine component.

4. Claim 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 46,47 rejected under 35 U.S.C. 102(b) as being anticipated by Cruz et al (1990) .

Rejections Maintained

6. Claims 46-49, 51-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for Pasteurella haemolytica vaccines that comprise any mutations in the leukotoxin C, A, B or D genes and the use of these strains as a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the claimed inventions, and to use them as vaccines for reasons of record in paper number 16, as applied to claims 46-47, paragraph 9.

7. Claims 46-49 and 51-62 (new claims) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the same reasons as applied to claims 48-49, made in paper number 16, paragraph 10. *This is a written description rejection.*

Allowable Subject Matter

8. Claims 40-44, upon processing the terminal disclaimer submitted April 7, 2000 and it being found proper define over the prior art of record.

Response to Amendment

9. The Declaration of Robert E. Briggs and Fred M. Tatum under 37 CFR 1.132 filed February 13, 2001 is insufficient to overcome the rejection of claims 46-49, 51-62 based upon 35 U.S.C. 112, first paragraph, enablement as set forth in the last Office action because: The Declaration is directed to the administration of a leukotoxin A mutation containing Pasteurella haemolytica bacteria, wherein the mutation was introduced by deletion of amino acids 34-378 of leukotoxin A. A strain of Pasteurella haemolytica bacteria that comprises the deletion of amino acids 34-378 of leukotoxin A was not described. The claims are not limited to the specific strain used for generating data in the Declaration submitted February 13, 2001. The data presented in the Declaration is not commensurate in scope with the now claimed invention. The data presented does not address vaccines that contain mutations in leukotoxin B,C or D genes, nor does it describe specific vaccine strains that contain these mutant nucleic acid sequences. No specific leukotoxin A deletion mutant containing strains are disclosed in the instant specification. The instant specification fails to teach how to make and use a deletion mutant which lacks amino acids 34-378 of leukotoxin A. No amino acid or nucleic acid sequences for any leukotoxins of Pasteurella are disclosed in the instant specification. The claims recite the word "gene". A gene

not only contains the open reading frame, but also encompasses all of the other sequences essential for expression (ie: leader sequence) . Where the amino acids described in the Declaration are exactly located has not been described, nor claimed, because no SEQ ID NO for Pasteurella haemolytica leukotoxin were provided in the instant Application. The Declaration, while interesting, is not commensurate in scope with the claimed invention.

Please Note: The examiner is responding to arguments directed to claims for which rejections have been maintained. Claims 40-44 have been indicated as containing allowable subject matter and arguments made by Applicant directed to these claims will not be discussed.

Response to Arguments

10. The rejection of claims 46-49, 51-62 under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for Pasteurella haemolytica vaccines that comprise any mutations in the leukotoxin C, A, B or D genes and the use of these strains as a vaccine is argued by Applicant through submission of a Declaration under 1.132 by the inventors Robert E. Briggs and Fred M Tatum, wherein the Declarative evidence is asserted to show a vaccine that "meets the requirements of claim 47". The efficacy of the leukotoxin A mutant containing strain is asserted to provide enablement for Pasteurella haemolytica bacterium that comprise a mutation in a leukotoxin B,C or D gene because of the interactive nature of the genes to achieve secretion of the gene product of leukotoxin A and further asserts that "a vaccine comprising a P.haemolytica

bacterium comprising a mutation in any of the leukotoxin B,C or D genes would be expected to provide protection against P.haemolytica challenge."

11. Applicant's arguments filed with respect to enablement of leukotoxin A,B, C and D mutation containing strains of Pasteurella have been fully considered but they are not persuasive because the Declaration presents data that is not commensurate in scope with the claimed invention.

The specification does not teach how to make or use, nor provide guidance to make or use a leukotoxin A mutant by deletion of amino acids 23-378 of the leukotoxin A gene and Cruz et al teach that "one should avoid over interpreting the significance of the completely inactive mutants since the effect of the deletions on toxin structure cannot be predicted" (see page 1937, col. 2, paragraph 2, last sentence).

The asserted enablement pointed to by Applicant is not described, suggested or shown in any working examples, nor is any guidance provided to the person of skill in the art to delete specific amino acids starting at the N-terminal region of leukotoxin A. The enablement rejection made of record over vaccines that comprises leukotoxin A, and C mutations is maintained, and now includes claims directed to leukotoxin B and D mutant strains of Pasteurella, for the same reasons set forth for mutant leukotoxin A and C strains in paper number 16, paragraph 9.

12. The rejection of claims 46-49 and 51-62 (new claims) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is argued by asserting that:

a. the Office has not met its burden of presenting evidence or reasons why persons of skill in the art would not recognize that Applicant's specification has not described the claimed invention recited in claims 48 and 49; and further asserts that

b. a mutation in a leukotoxin B or leukotoxin D gene which attenuates the bacterium "can be recognized without knowledge of the nucleotide sequences of the corresponding genes."

c. Applicant asserts that "[T]here is simply no legal requirement that the specification describe the nucleotide sequences of either the coding or regulatory regions of these genes to provide a written description of the subject matter of the claims" , specifically "bacteria with mutations in known genes."

d. A reference to Highlander et al, 1989, Figure 3 is asserted to provide written description of leukotoxin B and D genes, and provides both the nucleotide sequence of the operon and the amino acid sequences of the encoded proteins.

13. Applicant's arguments filed with respect to the lack of written description of the claimed mutant leukotoxin A,B,C or D containing vaccine strains of Pasteurella haemolytica have been fully considered but they are not persuasive because

a.the instant specification only provides a single sentence at page 7, that states "[O]ther genes in which mutations **may be desirable** (emphasis added) are genes in the leukotoxin operon (C,A,B, D)". No other discussion, suggestion, guidance, incorporation by reference, teaching

with respect to the type or location of the mutation is provided with respect to mutations in leukotoxin A,B,C or D genes, in the instant specification. The only statement made in the instant specification is in the future tense and the mutations "may be desirable". This statement does not provide written descriptive support that is enabling for the now claimed vaccines. The absence of description of the claimed inventions is the evidence that examiner has set forth as the basis for the lack of written description rejection made of record in paper number 16.

b. The examiner did not request or require the claims to recite specific sequences but stated that "The specification only discloses the existence of leukotoxin B, D and neuraminidase genes, but no coding regions, no cosmid clones, no restriction endonuclease fragments that encode the Pasteurella haemolytica neuraminidase are described" and that " No specific mutations are described that would result in a mutant Pasteurella haemolytica leukotoxin B or D bacterium". These statements are also true for mutant Pasteurella haemolytica leukotoxin C or A bacterium that would function as vaccine strains.

c. Arguments directed to the ability to screen for a Pasteurella haemolytica leukotoxin negative strain does not show that the mutation introduced is specific to the genes recited in the claims. Applicant's assertion that one of skill in the art could screen for mutant strains, is directed to an invitation to experiment. The claimed vaccines must evidence mutations specific to the recited leukotoxin genes, as well as function to induce protective immunity in a host animal upon challenge. No strains that evidence a leukotoxin mutation that also functions as a vaccine strain of Pasteurella haemolytica have been described in the instant specification.

The Highlander reference is argued to teach the leukotoxin operon of Pasteurella. While this is true, Highlander is silent with respect to vaccine compositions that comprise leukotoxin mutations. No suggestion for a Pasteurella haemolytica leukotoxin mutant vaccine strains could be found in the argued Highlander reference.

No specific leukotoxin A, B, C or D mutant strains of Pasteurella haemolytica that would serve to induce a protective immune response have been described in the instant specification.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

Claims 46-49 and 51-62 (new claims) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in paper number 16, as applied to claims 48-49, paragraph 10.

Conclusion

14. This is a non-final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

vgp
April 19, 2001

L. R. S.

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